

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty Dkt. 2551-69

MAERTENS, et al.

C# M#

Serial No. 09/995,860

C/A.U.

1648

Filed: November 29, 2001

Examiner: LI, BAO Q

Date: July 14, 2004

Title: PURIFIED HEPATITIS C VIRUS ENVELOPE PROTEINS FOR DIAGNOSTIC AND THERAPEUTIC USE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RULE 181 PETITION

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☐ **Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

| | | | | |
|----------------------------------------|----|----------------------|---|------------|
| Total effective claims after amendment | 0 | minus highest number | | |
| previously paid for | 20 | (at least 20) = | 0 | x \$ 18.00 |
| | | | | \$ 0.00 |
| Independent claims after amendment | 0 | minus highest number | | |
| previously paid for | 3 | (at least 3) = | 0 | x \$ 86.00 |
| | | | | \$ 0.00 |

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|----------------------------------------------------------------------------------------------|---------|
| If proper multiple dependent claims now added for first time, add \$290.00 (ignore improper) | \$ 0.00 |
|----------------------------------------------------------------------------------------------|---------|

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| Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$420.00/2 months; \$950.00/3 months) | \$ 0.00 |
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|---------------------------------------------|---------|
| Terminal disclaimer enclosed, add \$ 110.00 | \$ 0.00 |
|---------------------------------------------|---------|

| | |
|---------------------------------------------------------------------------------------------------------------|---------|
| <input type="checkbox"/> First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$770.00) | \$ 0.00 |
| <input type="checkbox"/> Please enter the previously unentered, filed | |
| <input type="checkbox"/> Submission attached | |

Subtotal \$ 0.00

| | |
|-------------------------------------------------------------------|----------|
| If "small entity," then enter half (1/2) of subtotal and subtract | -\$ 0.00 |
|-------------------------------------------------------------------|----------|

☐ Applicant claims "small entity" status. ☐ Statement filed herewith

| | |
|----------------------------------------------------------------|---------|
| Rule 56 Information Disclosure Statement Filing Fee (\$180.00) | \$ 0.00 |
|----------------------------------------------------------------|---------|

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|------------------------------------|---------|
| Assignment Recording Fee (\$40.00) | \$ 0.00 |
|------------------------------------|---------|

| | |
|--------------------------------------------------------------------------------------------------------------------------------------|------|
| Attached: Rule 181 Petition - Amendment, Information Disclosure Statement, PTO 1449 Form and 14 references filed separately herewith | 0.00 |
|--------------------------------------------------------------------------------------------------------------------------------------|------|

TOTAL FEE ENCLOSED \$ 0.00

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHUYE P.C.
By Atty: B. J. Sadoff, Reg. No. 36,663

Signature: 



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

MAERTENS, et al.

Atty. Ref.: 2551-69

Appl. No. 09/995,860

Group: 1648

Filed: November 29, 2001

Examiner: Li, Bao Q

For: PURIFIED HEPATITIS C VIRUS ENVELOPE PROTEINS FOR DIAGNOSTIC AND
THERAPEUTIC USE

* * * * *

July 14, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RULE 181 PETITION

The applicants hereby petition for the Commissioner to invoke his supervisory authority and review and reverse the Examiner's refusal to withdraw the restriction requirement in the above and at least examine the subject matter of the Examiner's Groups I-III in the present application.

The Examiner has made the restriction requirement final in the Office Action of January 15, 2004. Reconsideration and withdrawal of the restriction requirement were requested in the applicants Response of October 24, 2003.

An Amendment is filed herewith in response to the Office Action of January 15, 2004. Reconsideration and withdrawal of the restriction requirement are again requested in the attached Amendment.

The present Petition is being filed for consideration by the Commissioner in the event the Examiner again refuses to consider all of the subject matter of the Examiner's Groups I-III together and examine the subject matter of claims 41 and 42 with the subject matter of the Examiner's Groups I and II.

Consideration of the present Rule 181 Petition and a Decision on the same prior to issuance of a further Action from the Examiner is requested as issuance of a further Action prior to a Decision on the present Petition, in the event the Examiner refuses to take the requested action, will likely prejudice the applicants in continuing prosecution, likely with the issuance of a final rejection which will close prosecution prior to receiving the benefit of the Commissioner's Decision which may change the subject matter which is to be examined. In such circumstances, the applicants are put in the position of either responding to a final rejection where the issue of the subject matter to be examined is still pending before the Commissioner or await the Commissioner's Decision prior to responding to the likely final rejection. In either case, the applicants will likely be required to at least pay for extension fees while awaiting the Commissioner's Decision. A Decision on the present Petition is requested prior to the issuance of a further substantive Action from the Examiner in the event the Examiner continues in refusing to examine the subject matter of the Examiner's Groups I-III in a single application.

Claims 17-43 are pending. Claim 43 has been added in the attached Amendment based on unamended claim 40. Claim 40 has been amended and claim 43 added to correct multiple dependencies.

The Examiner's indication that claims 15-43 were pending as of the issuance of the Office Action dated January 15, 2004, is not understood and clarification is requested in the attached Amendment. Specifically, the Office Action of September 24, 2003 correctly indicated that claims 15-42 were pending and claims were not added in response to the Office Action of September 24, 2003. The above is submitted to be a correct listing of the claims. Clarification is requested however if the Patent Office believes otherwise.

The Examiner's consideration and examination of the subject matter of the Examiner's Groups I and II (as defined in the Office Action dated September 24, 2004) is acknowledged, with appreciation. The Examiner is again requested in the attached Amendment however, and the Commissioner is requested to invoke his supervisory authority to have the Examiner, also examine the subject matter of the Examiner's Group III with the subject matter of the Examiner's Groups I and II as allowability of the subject matter of the subject matter of Group II (as defined by claim 16 - "A therapeutic HCV vaccine composition comprising a therapeutically effective amount of at least one HCV single or specific oligomeric envelope E1 protein or a part thereof; and at least one of a pharmaceutically acceptable carrier, adjuvant or vehicle.") will also indicate the allowability of the subject matter of the Examiner's Group III (as defined by claim 17 - "A therapeutic HCV vaccine composition comprising a therapeutically effective amount of a combination of at least two HCV single or specific oligomeric envelope E1 proteins or parts thereof wherein said at least two E1 proteins or parts thereof are derived from different HCV genotypes, subtypes or isolates; and at least one of a pharmaceutically acceptable carrier, adjuvant or vehicle. "). That is, the addition of at least one additional

E1 protein or part thereof to the vaccine of claim 16, even if derived from a different HCV genotype, subtype or isolate, as recited in claim 17, will not require an additional search of the art since patentability may be based on the allowability of the at least one HCV E1 protein or a part thereof of claim 16.

Moreover, just as restriction between the Examiner's Groups I and II may have limited the applicants opportunity to amend the claims during prosecution as, for example, the subject matter of claim 16 is an embodiment of claim 15, requirement of restriction between the subject matter of the Examiner's Groups I and II, and the Examiner's Group III may also limit the applicants opportunity to amend the claims during prosecution as, for example, the subject matter of claim 17 is an embodiment of the subject matter of claims 15 (i.e., Group I) and claim 16 (i.e., Group II). The Commissioner is urged to appreciate that claim 16 provides a vaccine composition which comprises at least one HCV envelope E1 protein or a part thereof.

Further, the Examiner has rejected claims 15 and 16, among other claims, as allegedly being obvious in view of claims 16 and 21 of the Assignee's prior U.S. Patent No. 6,635,257. See, page 9 of the Office Action dated January 15, 2004. The Commissioner is urged to appreciate that claim 16 of the cited patent provides a composition comprising an oligomeric particle of claim 1, 7, 9, 10 or 11 of the cited patent and at least one of an excipient, diluent, carrier or adjuvant. Claim 11 of the cited patent, from which claim 16 of the cited patent depends, provides an oligomeric particle consisting essentially of HCV envelope proteins and having a diameter of 1 to 100 nanometer, wherein said envelope proteins, or parts thereof, are a mixture consisting of HCV envelope proteins from one strain or genotype of HCV and at least one other strain

or genotype of HCV. Accordingly, to the extent the Examiner believes the present claims 15 and 16, which define the subject matter of the present Examiner's Groups I and II, are obvious in view of claim 16 of the cited patent, the subject matter of a composition containing a combination of envelope proteins from at least two strains or genotypes of HCV, as recited in claims 11 and 16 of the cited patent and claim 17 of the present application (i.e., Group III of the present application), does not define an independent and distinct invention and the subject matter of the Examiner's Group III should be examined with the subject matter of the Examiner's Groups I and II. The Examiner's restriction requirement is inconsistent with the Examiner's double patenting rejection as well as the Patent Office's prior examination of the assignee's prior U.S. Patent No. 6,635,257.

Examination of all the subject matter of the Examiner's Groups I-III in a new non-final Office Action is requested.

Finally, the Examiner's withdrawal of claims 41 and 42 from consideration as being included in the subject matter of the Examiner's Group III is not understood as these claims depend from claims 23 and 24, respectively, which the Examiner has included in the subject matter of the Examiner's Group II, and substantively examined. Claims 41 and 42 further specify that the mammal recited in claims 23 and 24, respectively, is a human. Claims 41 and 42 are submitted to be improperly included in the subject matter of the Examiner's Group III. Examination of claims 41 and 42 with the subject matter of the Examiner's Groups I and II is requested.

As noted above, the present Rule 181 Petition is filed being filed for consideration by the Commissioner in the event the Examiner again refuses to consider

all of the subject matter of the Examiner's Groups I-III together and examine the subject matter of claims 41 and 42 with the subject matter of the Examiner's Groups I and II.

Favorable consideration of the present Rule 181 Petition and a Decision on the same prior to issuance of a further Action from the Examiner is requested as issuance of a further Action prior to a Decision on the present Petition will likely prejudice the applicants in continuing prosecution, likely with the issuance of a final rejection which will close prosecution prior to receiving the benefit of the Commissioner's Decision which may change the subject matter which is to be examined. In such circumstances, the applicants are put in the position of either responding to a final rejection where the issue of the subject matter to be examined is still pending before the Commissioner or await the Commissioner's Decision prior to responding to the likely final rejection. In either case, the applicants will likely be required to at least pay for extension fees while awaiting the Commissioner's Decision. A Decision on the present Petition is requested prior to the issuance of a further substantive Action from the Examiner in the event the Examiner continues in refusing to examine the subject matter of the Examiner's Groups I-III in a single application.

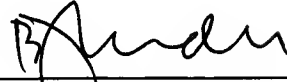
A Petition fee is not believed to be required for consideration of the present Petition as the Petition need only be considered in the event of Patent Office error in the Examiner not examining the subject matter of the Examiner's Groups I-III in this application. The Office is authorized however by the present paper and attached cover sheet to charge the undersigned's Deposit Account No. 14-1140 for any missing or deficient fee believed to be required for consideration of the present Petition.

MAERTENS, et al.
Appl. No. 09/995,860
July 14, 2004

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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